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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

ERIN ALLEN, on behalf of herself and all
others similarly situated,

Plaintiffs,

v.

CONAGRA FOODS INC., a Delaware
corporation,

Defendant.

Case No.: 3:13-CV-01279-WHO

Assigned to the Hon. William H. Orrick
Courtroom 2

**DEFENDANT CONAGRA BRANDS, INC.'S
MOTION FOR SUMMARY JUDGMENT**

*Filed concurrently with Declaration of Jamie S.
George; [Proposed] Order*

Date: July 22, 2020
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Courtroom.: 2

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NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE THAT on July 22, 2020 at 2:00 p.m., or as soon thereafter as the matter may be heard, in the United States District Court, Northern District of California, San Francisco Division, located at 450 Golden Gate Avenue, San Francisco, CA 94102, before the Honorable William H. Orrick, defendant Conagra Brands, Inc., f/k/a ConAgra Foods Inc. (“Conagra” or “Defendant”) will, and hereby does, move this Court to grant summary judgment, or, in the alternative, partial summary judgment, dismissing Plaintiffs’ claims, including the claims of named Plaintiff Erin Allen and the certified class, on the grounds that there is no genuine dispute of material fact and that Conagra is entitled to judgment as a matter of law.

This Motion is made pursuant to Federal Rule of Civil Procedure 56, and is based on this Notice of Motion, the accompanying Memorandum of Points and Authorities, and on such other written and oral argument as may be presented to the Court.

DATED: June 17, 2020

**ANGELA M. SPIVEY
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/s/ Angela M. Spivey
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STATEMENT OF ISSUES TO BE DECIDED
CIVIL L.R. 7-4(A)(3)

This motion raises the following issues:

1. **Express Preemption.** Can Plaintiffs impose product label requirements that are “not identical” to FDA regulations according to the plain language of those regulations and FDA’s controlling interpretation?
2. **Primary Jurisdiction.** Should the Court dismiss or stay the case under the doctrine of primary jurisdiction in light of FDA’s active involvement in this space?
3. **Actual Reliance.** Should Plaintiff Erin Allen’s claims under the post-2009 version of the label be dismissed for lack of actual reliance in light of her admission that she did not view and was unaware of the “per serving” portion of the post-2009 challenged labeling claim?
4. **Scienter.** Are Plaintiffs able to prove scienter where the challenged claims are based on Conagra’s reasonable interpretation of the disputed federal RACC regulation?
5. **Consumer Deception.** Would a reasonable consumer be deceived by a product label that discloses the information necessary to dispel any confusion?
6. **Damages.** Can Plaintiffs rely on a damages model that is incapable of producing “prices” or “market value”—the measure of damages Plaintiffs claim?

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiffs’ claims in this lawsuit are all premised on Conagra allegedly using “artificially small ‘serving sizes’” for Parkay Spray “that fail to account for the manner in which these products are customarily consumed.” Dkt. 214 at ¶ 6. But food manufacturers like Conagra are required to calculate serving sizes using the FDA-mandated reference amount for the applicable product category and “cannot deviate from the reference amount simply because they believe that such deviation is supported by food consumption data.” 58 Fed. Reg. 2229, 2273 (Jan. 6, 1993). Indeed, “it is the agency, not the courts or consumers, who set these standards.” *Pardini v. Unilever United States, Inc.*, No. 13-cv-1675, 2014 U.S. Dist. LEXIS 7900, at *15 (N.D. Cal. Jan. 22, 2014) (citing 21 C.F.R. § 101.12(a)(1)(2)). If a food manufacturer is “not sure about which product category [its] specific products belong,” it “should refer to [the FDA’s list of exemplar products] or consult with the agency.” 58 Fed. Reg. 2229, 2241 (Jan. 6, 1993). Conagra has done both. The FDA’s list of exemplar products makes clear that Parkay Spray should use the “Fats and Oils: Spray types” category, which includes “**all types** of cooking sprays”—like Parkay Spray. Dkt. 222-1 at 23 (emphasis added). Conagra has also consulted with FDA, which advised in unequivocal terms, “this product belongs in the ‘Fats and Oils: Spray types’ product category with a RACC [reference amount customarily consumed] of 0.25 g.”¹ These regulations, and FDA’s clarifying instruction, leave no room for discretion. Conagra **must** use the 0.25 gram reference amount for “Fats and Oils: Spray types” corresponding to a serving size of 1 spray for cooking. Plaintiffs’ requested relief asks the Court to order Conagra to disregard and disobey FDA’s express direction (opening Conagra up to an FDA enforcement action), to issue an injunction essentially requiring Conagra to use a RACC that FDA has said is incorrect, and to award damages against Conagra for doing precisely what the relevant regulations mandate.

Doctrines like preemption, *Auer* deference, and primary jurisdiction exist for this very reason: so that a party is not subject to multiple, inconsistent interpretations of the same statute or regulation and does not face judicially imposed liability for following administrative agency guidance. Traveling

¹ Declaration of Jamie S. George (“George Decl.”), Ex. 1 (Sept. 6, 2019 FDA Letter).

1 under any of those doctrines, summary judgment should be granted in Conagra's favor. Under the
2 plain language of the RACC regulation alone, the proper product category for Parkay Spray (a spray-
3 dispensed, vegetable oil-based food product) is "Fats and Oils: Spray types," and Plaintiffs' efforts to
4 impose a different requirement than that which arises under the federal regulations are expressly
5 preempted. *See Pardini*, 2014 U.S. Dist. LEXIS 7900, at *14-18 (finding that "according to the
6 regulations," the proper category for near-identical, competing product was Fats and Oils: Spray types
7 and holding that plaintiffs' claims were preempted). Even if the RACC regulation could be read in
8 such a manner that another product category could equally apply to Parkay Spray (in direct conflict
9 with *Pardini*), FDA has now definitively and authoritatively spoken, and stated that Conagra is using
10 the correct RACC. FDA's position, set forth in a September 6, 2019 letter signed by FDA's Director
11 of the Office of Nutrition and Food Labeling, is entitled to controlling *Auer* deference, as recently
12 confirmed by the U.S. Supreme Court's *Kisor v. Wilkie* decision. That letter also shows that FDA is
13 already monitoring products in this space. The Court should decline to intervene where FDA is
14 actively regulating and defer to FDA's primary jurisdiction, especially where the claims at issue
15 implicate FDA's expertise in choosing the appropriate serving size.

16 Plaintiffs' claims also fail on the merits—in whole or in part—for additional, independent
17 reasons unrelated to the RACC regulation and FDA's dispositive guidance. First, all of class
18 representative Erin Allen's claims based on the post-2009 version of the Parkay Spray label must be
19 dismissed because she did not view—and was not aware of—the additional zero grams fat/zero
20 calories "*per serving*" language until after she filed suit. As a matter of law and common sense, she
21 could not have relied on that challenged claim. The Court has already concluded that the pre- and
22 post-2009 labels were materially different, which "requires that each class be divided into two time
23 periods—one before and another after the label change—as plaintiffs suggest." Dkt. 267 at 15.
24 Accordingly, once Ms. Allen's post-2009 label claims are dismissed, there will be no class
25 representative for that separate subclass and that subclass must be decertified. Second, Plaintiffs'
26 fraud claims and plea for exemplary damages must be dismissed because Conagra's reliance on a good
27 faith interpretation of a regulation forecloses any possibility that the scienter requirement can be met
28 as a matter of law. Conagra's more-than-reasonable interpretation of the RACC regulation has been

1 validated by FDA in its letter and by the Honorable Samuel Conti in *Pardini*. Third, Plaintiffs' claims
 2 should all be dismissed because any consumer confusion over the fat and caloric content of Parkay
 3 Spray was remedied by other disclosures on the front of the packaging and nutrition panel stating that
 4 Parkay Spray is "44% vegetable oil" and contains soybean oil and buttermilk.

5 Lastly, even if Plaintiffs' claims did not fall on their merits, Plaintiffs have not presented
 6 competent evidence of damages. Although courts in the past have signed off on conjoint damages
 7 models like the one Plaintiffs rely on, they usually did so without a probing inquiry. Recent decisions
 8 that have actually dug in on the issues presented by conjoint analysis have found that the methodology
 9 is incapable of measuring the difference between *prices* in the actual and but-for world, which is the
 10 measure of damages claimed by Plaintiffs. Conjoint analysis looks only at what surveyed consumers
 11 say they would pay (willingness to pay), not how consumers and sellers would actually interact in a
 12 marketplace (market price). As one court explained in a case applying California law, where plaintiffs
 13 rely solely on such a conjoint analysis and "point to no other evidence from which a factfinder could
 14 find damages based on a difference in value[,] there is an 'absence of evidence' on an 'essential
 15 element' of Plaintiffs' claims for such damages" and the court must grant summary judgment. *In re*
 16 *GM LLC Ignition Switch Litig.* ("In re GM"), 407 F. Supp. 3d 212, 241 (S.D.N.Y. 2019).

17 For all of these reasons, Conagra is entitled to summary judgment.

18 **II. UNDISPUTED FACTS**

19 **A. Parkay Spray**

20 Parkay Spray is a spray-dispensed mixture of water, oil, and buttermilk formulated to impart a
 21 "Fresh & Creamy" taste. Dkt. 110-26 (2007 label), 110-28 (2009 label), 110-30 (2011 label); George
 22 Decl., Ex. 2 (Declaration of Annette W. Hottenstein ("Hottenstein Decl.") at Table 2). Parkay Spray
 23 is neither butter, nor margarine, which both have "standards of identity" established by FDA. George
 24 Decl., Ex. 3 (4/30/20 Hottenstein Dep. at 212:3-214:12). Parkay Spray is intended to be used as both
 25 a spray to lubricate cookware and as a topping to be sprayed directly on food. *See* Dkt. 110-26, 110-
 26 28, 110-30 (disclosing serving sizes for both label-promoted uses). Although Plaintiffs apparently
 27 dispute the efficacy of Parkay Spray as a cooking spray, the unrebutted record evidence shows:

- 28 • **Many consumers use Parkay Spray as a cooking spray.** *See* Dkt. 253-24 (reporting survey

results showing 43.5% of respondents used Parkay Spray as a non-stick cooking spray compared to 27.8% of respondents who used Parkay Spray as a topping when asked open-ended question; 78.3% used Parkay Spray as non-stick cooking spray compared to 50.5% as a topping when asked closed-ended question).

- **In Plaintiffs' expert's own test, Parkay Spray was successfully used as a cooking spray.** See George Decl., Ex. 2 (Hottenstein Decl. at ¶ 39 (reporting that no food stuck to the pan when Parkay Spray was used)); George Decl., Ex. 3 (4/30/20 Hottenstein Dep. at 229:8-13 (agreeing that she was able to spray Parkay Spray in a pan, cook a piece of chicken with it, and the chicken was cooked through and edible)).
- **In fact, in Plaintiffs' expert's own test, Parkay Spray actually performed similarly to or better than PAM cooking spray.** See George Decl., Ex. 3 (4/30/20 Hottenstein Dep. at 227:13-17 ("Q: So organoleptically, wasn't the chicken cooked with one spray of Parkay Spray pretty similar to or maybe even better than the chicken cooked with one second of PAM? A: You can conclude that, yes."); *id.* at 227:25-228:2 ("Q: Okay. So one spray of Parkay Spray outperformed one second of PAM in those ways, right? A: Yes."); *id.* at 228:16-23 ("Q: So didn't Parkay Spray perform similarly to PAM in this test, as well? A: Yes. Q: In fact, it outperformed PAM when it came to the crispiness of the chicken, right? A: Yes. The moistness of the chicken? A: Yes.")).

The listed serving size for Parkay Spray is 1 spray (0.2 grams) for cooking and 5 sprays (1 gram) for topping, as displayed on the federally mandated Nutrition Facts Panel. Dkt. 110-26, 110-28, 110-30. It is undisputed that at both of these serving sizes, Parkay Spray contains less than 5 calories and less than 0.5 grams of fat. Dkt. 222 at 28. It is likewise undisputed that "[w]here a single serving of a particular product contains less than 0.5 grams of fat, FDA regulations provide that the product's label shall express the fat content per serving as zero" and "calories per serving may be expressed as zero where a product contains less than five calories per serving." *Pardini*, 2014 U.S. Dist. LEXIS 7900, at *10. Parkay Spray's label also discloses on the front panel that it contains "44% vegetable oil" and on the back panel ingredient list that two of the most prominent ingredients are soybean oil and buttermilk. Dkt. 110-26, 110-28, 110-30.

The front label for Parkay Spray during the beginning of the class period through late 2009 included the representations "Fat Free" and "Zero Calories" (the "pre-2009 label"). See Dkt. 110-26. In approximately October 2009, "Fat Free" was changed to "0g Fat Per Serving" and "Zero Calories" was changed to "Zero Calories Per Serving" (the "post-2009 label"). Dkt. 252-14, 110-28, 110-30. Plaintiffs allege that these representations are false and deceptive even though they are literally true for the disclosed serving sizes (according to FDA's rounding rules for fat and calories) because Parkay

1 Spray uses “artificially small” serving sizes. Dkt. 214 at ¶ 28.²

2 **B. FDA’s September 6, 2019 Letter**

3 On February 26, 2019, regulatory counsel for Conagra wrote to FDA and requested
4 clarification on the RACC for Parkay Spray, specifically whether Parkay Spray belongs in the “Fats
5 and Oils: Spray types” category or (as Plaintiffs contend) the “Butter, margarine, oil, shortening”
6 category. *See* Dkt. 262-2. On September 6, 2019, FDA responded via letter signed by Dr. Douglas
7 Balentine, Director of the Office of Nutrition and Food Labeling (“ONFL”) at the Center for Food
8 Safety and Applied Nutrition (“CFSAN”). *See* George Decl., Ex. 1. The ONFL is responsible for
9 “policy development and management of food and nutrition labeling”; developing “regulations,
10 compliance policy, position papers, regulatory guidelines and advisory opinions” for such matters;
11 providing expert advice to the CFSAN Director; and directing major FDA nutrition labeling initiatives.
12 *See* George Decl., Ex. 4 (FDA Staff Manual). The Director of the ONFL reports to the Director of the
13 CFSAN, who reports to the Office of the Commissioner. George Decl., Ex. 5 (FDA Org. Charts).

14 In that letter, FDA agreed that Parkay Spray “belongs in the ‘Fats and Oils: Spray types’
15 product category with a RACC of 0.25 g” and accordingly clarified “that the appropriate RACC for
16 Parkay Spray is 0.25 g.” George Decl., Ex. 1. FDA further explained:

17 In February 2018, FDA issued a final guidance document that provides examples of
18 products that belong in each of the product categories included in Title 21 of the Code of
19 Federal Regulations (21 CFR), section 101.12(b). This guidance document was intended
20 to help industry identify the product category to which specific products belonged. In the
21 “Severing Size” final rule, on which this guidance document is based, the agency revised
the examples for the “Spray types” product category in the “Fats and Oils” category to
include “all types of cooking sprays (e.g., cooking spray olive oil).” The agency made this
revision to clarify that this product category applies to all types of oil-based sprays used in
cooking.

22 **C. Class Representative Erin Allen**

23 Class representative Erin Allen “purchased Parkay Spray buttery topping during the entrie [sic]
24 class period, including the period prior to October 14, 2009, when the Parkay Spray label included the
25 ‘FAT FREE • ZERO CALORIES’ language.” Dkt. 197 at 2. However, Ms. Allen did not view, and

26 _____
27 ² It is undisputed that if “Fats and Oils: Spray types” is the correct RACC product category: (i) the
28 serving size of Parkay Spray would contain an amount of fat and calories that can (and, in the case of
fat, must) be rounded down to zero; and (ii) as a result, Conagra is permitted to make zero fat and zero
calories claims outside of the Nutrition Facts Panel. *See* 21 C.F.R. §§ 101.60(b), 101.62(b).

1 was not aware of, the post-October 2009 addition of the “per serving” qualifier until after she filed
 2 this lawsuit. According to her sworn deposition testimony, “I believe that all the bottles I purchased
 3 said, ‘0 Grams Fat, 0 Calories.’” George Decl., Ex. 6 (8/28/14 Allen Dep. 85:24-25). When pressed
 4 whether the bottles she purchased included the “per serving” language, Ms. Allen responded, “I never
 5 looked at – I – until recently, *I did not see the ‘per serving,’ no.*” *Id.* at 86:3-4 (emphasis added).
 6 She then clarified that by “recently” she meant “the past couple of months” (i.e. approximately June
 7 2014) and that she had not realized there was a difference between the pre- and post-2009 labels at the
 8 time the First Amended Complaint was filed in September 2013. *Id.* at 86:5-22.

9 **III. PROCEDURAL HISTORY**

10 The Consolidated Second Amended Complaint, filed on September 12, 2018, is the operative
 11 pleading. On December 10, 2018, the Court ruled on Conagra’s Motion to Dismiss, dismissing with
 12 prejudice Plaintiffs’ claims predicated on a missing asterisk on the Parkay Spray label, as well as all
 13 common law claims asserted under the laws of states other than California. On July 22, 2019, the
 14 Court certified two multi-state subclasses and four individual state subclasses represented by five class
 15 representatives (one from California and four from outside the state). Each class was further divided
 16 into two periods, “one from before the label change and one from after the label change.” Dkt. 267 at
 17 42-43. After inviting Conagra to file a motion for reconsideration related to personal jurisdiction, Dkt.
 18 275, the Court dismissed the claims brought by the non-California named plaintiffs and decertified the
 19 subclasses represented by non-California named Plaintiffs on October 15, 2019. Dkt. 280 at 7.

20 In the wake of that ruling, Erin Allen (the lone California resident) is the only remaining class
 21 representative. Ms. Allen represents an individual state class of California consumers asserting claims
 22 for: (i) fraud by concealment; (ii) breach of express warranty; (iii) intentional misrepresentation; (iv)
 23 violation of California’s False Advertising Law (“FAL”); and (v) violation of the Consumers Legal
 24 Remedies Act (“CLRA”). In addition, Ms. Allen represents a subclass of California and Hawaii
 25 consumers asserting claims for: (i) violation of California’s Unfair Competition Law (“UCL”) and (ii)
 26 violation of Hawaii’s Unfair and Deceptive Acts or Trade Practices Act (“UDAP”). Plaintiffs are only
 27 pursuing injunctive relief on behalf of Hawaiian consumers. *See* Dkt. 285 at 2; 287 at 4; 287-1 at 3.
 28 Finally, Ms. Allen has asserted a quasi-contract/unjust enrichment claim in her individual capacity.

IV. LEGAL STANDARD

To prevail on summary judgment, a movant must show the absence of a genuine issue of material fact with respect to an essential element of the non-moving party's claim. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); Fed. R. Civ. P. 56(a). Once the movant has made this showing, the burden then shifts to the party opposing summary judgment to identify "specific facts showing there is a genuine issue for trial." *Id.* The party opposing summary judgment must present affirmative evidence from which a jury could return a verdict in that party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 257 (1986). But conclusory and speculative testimony does not raise genuine issues of fact and is insufficient to defeat summary judgment. *Thornhill Publ'g Co., Inc. v. Gen. Tel. & Elec. Corp.*, 594 F.2d 730, 738 (9th Cir. 1979). Courts may also grant "partial summary judgment" to "selectively fillet a claim or defense without dismissing it entirely." *Finjan, Inc. v. Blue Coat Sys., LLC*, 283 F. Supp. 3d 839, 850 (N.D. Cal. 2017) (citation omitted).

V. ARGUMENT

A. Plaintiffs' Requested Relief Requires the Court, and Conagra, to Ignore the Plain Language of the RACC Regulation and Disregard FDA's Clear Instruction

Plaintiffs attempt to impose liability based on an interpretation of 21 C.F.R. § 101.12(b)—the binding regulation setting forth RACCs that food manufacturers "shall" use in determining serving sizes for specific products—that is unsupported by its plain language and directly conflicts with the FDA's interpretation. Critically, Plaintiffs also seek injunctive relief which would effectively require Conagra to re-label Parkay Spray in a manner that directly conflicts with the FDA's express directions to Conagra. To avoid the untenable situation where Conagra is forced to choose between following regulatory guidance or facing legal liability, the Court should: (i) dismiss Plaintiffs' claims as expressly preempted based on § 101.12(b)'s plain language and FDA's controlling interpretation; or (ii) defer to the FDA's primary jurisdiction.

1. Plaintiffs' Claims Are Expressly Preempted Whether Relying on the Plain Language and Structure of the RACC Regulation or FDA's Controlling Guidance

Federal law expressly preempts any effort to "directly or indirectly" impose state law requirements that are "not identical to" the federal nutrition labeling requirements provided for by the Nutrition Labeling and Education Act ("NLEA"), which includes requirements related to serving sizes

1 and nutrient content claims. 21 U.S.C. § 343-1(a). “Not identical to” in this context means “different
 2 than” or “in addition to.” *See* 21 C.F.R. § 100.1(c)(4). Plaintiffs’ claims are all preempted here
 3 because they are seeking to declare unlawful the very thing federal law **requires**: using the “Fats and
 4 Oils: Spray types” RACC product category to determine Parkay Spray’s serving size. Moreover, as
 5 this Court previously found, if Conagra selected the correct RACC – as FDA has now confirmed –
 6 each of Plaintiffs’ claims are preempted because (i) the serving size of Parkay Spray would contain an
 7 amount of fat and calories that can (and, in the case of fat, must) be rounded down to zero; and (ii)
 8 Conagra is permitted to make zero fat and zero calories claims on the product label. *See* Dkt. 231 at
 9 8 (finding that if Conagra selected correct RACC, “Parkay Spray is appropriately labeled as zero fat
 10 and zero calorie under federal law”); *see also* 21 C.F.R. §§ 101.60(b), 101.62(b).

11 Traditional tools of statutory/regulatory interpretation and construction show that “Fats and
 12 Oils: Spray types” is the correct RACC product category. But even if the RACC regulation was
 13 genuinely susceptible to any other reasonable meaning, FDA—the agency responsible for developing
 14 and advising on the appropriate product category—has definitively concluded that “this product
 15 belongs in the ‘Fats and Oils: Spray types’ product category with a RACC of 0.25 g.” George Decl.,
 16 Ex. 1. The agency’s authoritative, expertise-based, considered, and fair interpretation is entitled to
 17 controlling “*Auer* deference,” as recently reaffirmed in *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019).

18 **a. Aided by the Traditional Tools of Interpretation, “Fats and Oils: Spray**
 19 **Types” Is the Correct RACC Product Category**

20 At the motion to dismiss stage, the Court concluded that Plaintiffs “adequately **alleged** that
 21 Parkay Spray is imitation butter and belongs in the same reference amount category as butter.” Dkt.
 22 231 at 15 (emphasis added). At the same time, the Court acknowledged that Parkay Spray can be
 23 used—and is indeed promoted—as a cooking spray (which belongs in the “Spray types” product
 24 category), and indicated that Conagra could rely on such arguments as the case proceeds. *Id.* at 15-
 25 16. In the interim, Plaintiffs have attempted to create a question of fact as to whether Parkay Spray is
 26 more organoleptically similar to butter or margarine, on the one hand, or PAM spray, on the other.
 27 *See generally* George Decl., Ex. 2 (Hottenstein Decl.).³ Despite Plaintiffs’ efforts, there is no genuine

28 ³ In her deposition, Plaintiffs’ expert confirmed that her opinion is limited to whether Parkay Spray is

1 issue of material fact that prevents the Court from ruling that, as a matter of law, “Fats and Oils: Spray
2 types” is the correct RACC product category.

3 **First**, beginning with the plain language of 21 C.F.R. § 101.12(b)—“the starting point for its
4 interpretation,” *Solis v. Saenz*, 60 F. App’x 117, 119 (9th Cir. 2003)—the **only** product category that
5 applies on its face to Parkay Spray is “Fats and Oils: Spray types.” Parkay Spray consists of soybean
6 oil suspended in water (and therefore is a fat/oil) and is dispensed via a spray pump (and therefore is
7 a spray type). *See, e.g.*, George Decl., Ex. 2 (Hottenstein Decl. at Table 2). Parkay Spray is literally,
8 inarguably, and unmistakably a spray-type fat and oil. To find Parkay Spray is not a “Fats and Oils:
9 Spray type” is to disregard that plain language of the regulation.

10 **Second**, even if Parkay Spray could potentially be placed in the “Butter, margarine, oil,
11 shortening category”—either as an oil (which it is, in part) or a butter or margarine substitute (which
12 it is not, at all)—under basic rules of statutory construction, as to two potentially applicable categories,
13 the more specific should govern the more general. *U.S. ex rel. Welch v. My Left Foot Children’s*
14 *Therapy, LLC*, 871 F.3d 791, 797 (9th Cir. 2017) (explaining canon that specific provisions and terms
15 control over general ones is a “cardinal rule” of textual interpretation). The category “Butter,
16 margarine, oil, shortening” potentially describes Parkay Spray from a compositional perspective. But
17 the category “Fats and Oils: Spray types” describes Parkay Spray from a compositional (oil-based)
18 and functional (spray-dispensed) perspective. And, while all “Fats and Oils: Spray types” fall within
19 the “butter, margarine, oil, shortening” category, the converse is not true. Put differently,
20 “[m]anufacturers must use the defaulted serving size of one tablespoon for any ‘Fat and Oil’ unless
21 the product fits within a more specific subcategory. . . . The subcategory here, according to the

22
23 more similar to butter/margarine than it is to PAM—not whether Parkay Spray is more similar to
24 butter/margarine than it is to **any other** non-PAM cooking spray. *See* George Decl., Ex. 3 (4/30/20
25 Hottenstein Dep. at 62:4-15). While that limitation alone renders her opinion unhelpful, Plaintiffs’
26 expert also answers an irrelevant question. Nowhere does the applicable regulation require the Court
27 to make organoleptic comparisons between product categories. The organoleptic properties of Parkay
28 Spray only come into play for substitute products, and Parkay Spray is not a “substitute” for “Fats and
Oils: Spray types”—it literally falls in that category. By way of illustration, banana chips literally fall
within the “Snacks: All varieties, chips, pretzels, popcorn, . . . fruit and vegetable-based snacks (e.g.,
fruit chips) . . .” category, and a manufacturer is not first required to show they are more
organoleptically similar to potato chips than to fresh bananas for the former category to apply.

1 regulations . . . is ‘Fats and Oils: Spray Type.’” *Pardini*, 2014 U.S. Dist. LEXIS 7900, at *14.⁴

2 **Third**, the structure of the RACC regulation reveals that the manner in which a product is
 3 served, here a spray dispenser, matters for purposes of selecting the appropriate product category. For
 4 example, 21 C.F.R. § 101.12(b) includes separate product categories, with different reference amounts,
 5 for grated versus block cheese, for dried versus fresh or frozen vegetables, and for breads versus bread
 6 sticks. This structure is consistent with the stated purpose of the RACC regulation, which was to
 7 establish uniform reference amounts corresponding to the amount people typically consumer per
 8 eating occasion. *See* 21 C.F.R. § 101.12(a). In this way, the RACC regulation recognizes that
 9 consumption patterns differ based on the product’s form.

10 **Fourth**, the measurements for the reference amounts associated with each product category
 11 confirm that Parkay Spray belongs in the “Fats and Oils: Spray types” category with a reference
 12 amount of 0.25 grams, rather than in the “Butter, margarine, oil, shortening” category with a reference
 13 amount of 1 tablespoon.⁵ It would be impractical, if not impossible, for a consumer to measure Parkay
 14 Spray in terms of tablespoons. A consumer would have to spray well over 50 times to measure one
 15 tablespoon of Parkay Spray. Dkt. 262-2. In the process, some of the product would likely be wasted
 16 as the mist portion of the spray did not land in the measuring spoon. In contrast, measuring Parkay
 17 Spray in fractions of a gram is easily accomplished given that each spray is 0.2 grams.

18 **Fifth**, in addition to the impracticality of measuring an entire tablespoon of Parkay Spray, the
 19 product was not developed to be consumed in that amount. According to Plaintiffs’ expert, Parkay
 20 Spray’s flavor is 1.5 to 2 times more intense than butter and margarine; Parkay Spray is **3 times** saltier
 21 than margarine and **9 times** saltier than butter, and consuming an entire tablespoon of Parkay Spray at
 22 once can be unpalatable. George Decl., Ex. 2 (Hottenstein Decl. at Table 1); George Decl., Ex. 3
 23 (Hottenstein Dep. at 208:9-12). That level of salt and intensity of flavor further belies Plaintiffs’

24 _____
 25 ⁴ The structure of the RACC regulation also confirms that a manufacturer must choose the most
 26 specific product category out of all potentially applicable categories, given that there are numerous
 overlapping categories. For example, Cheerios technically fit in the “Grains” category, but more
 appropriately should be classified as “Breakfast cereals, ready to eat.”

27 ⁵ The “Fats and Oils: Spray types” category also includes a recommended label statement expressing
 28 the serving size in seconds of spray, but footnote 4 to 21 C.F.R. § 101.12(b) clarifies that the “label
 statements are meant to provide examples of serving size statements that may be used on the label, but
 the specific wording may be changed as appropriate for individual products.”

1 contention that Parkay Spray's correct RACC is one tablespoon.

2 ***Sixth***, the un rebutted consumption survey evidence in this case is consistent with Parkay Spray
 3 falling in the "Fat and Oils: Spray type" category rather than "Butter, margarine, oil, shortening"
 4 category. Specifically, survey respondents overwhelmingly consumed only 1-5 sprays of Parkay
 5 Spray, and almost no respondents used 50 or more sprays, the serving size advocated by Plaintiffs.
 6 While consumption data cannot serve as a basis for deviating from the reference amounts established
 7 by FDA (which are based on FDA's own consumption surveys), 58 Fed. Reg. 2229, 2273 (Jan. 6,
 8 1993), the fact that consumers actually use 1-5 sprays, and not 50 or more, further substantiates that
 9 Conagra has selected the appropriate RACC product category. Dkt. 253-24 at 23-24.

10 ***Seventh***, guidance issued by FDA in 2018 confirms that the "Fats and Oils: Spray types"
 11 category includes all oil-based sprays used for cooking. The 2018 guidance lists "All types of cooking
 12 sprays" as exemplar products falling in that category,⁶ which is significantly broader than previous
 13 guidance listing only "Nonstick cooking sprays (e.g., PAM)." See Dkt. 222 at 25-27. Parkay Spray
 14 is literally an oil spray used for cooking. It was designed, marketed, and positioned as a cooking spray.
 15 And, notwithstanding Plaintiffs' claims that 100% oil cooking sprays are more suitable, Plaintiffs'
 16 own expert confirmed that Parkay Spray functions appropriately as a cooking spray, and in some ways
 17 actually *outperforms* PAM (the cooking spray FDA listed by name in its previous guidance). See
 18 George Decl., Ex. 3 (4/30/20 Hottenstein Dep. at 227:13-24; *id.* at 228:4-23).

19 ***Eighth***, while Plaintiffs attempt to create a fact question as to whether Parkay Spray should be
 20 classified as a butter/margarine substitute rather than a spray-type oil,⁷ the numerous concessions made
 21 by Plaintiffs' expert actually confirm that they cannot prove that Parkay Spray is a substitute product
 22 and that no reasonable jury could return a verdict in their favor. Moreover, the Court need not even
 23 consider Plaintiffs' substitute argument given that the plain language of the regulation, its structure,
 24 and the interpretive canons all point to "Fats and Oils: Spray types" as the appropriate category.⁸

25 ⁶ The 2018 guidance provides examples of products falling in each category "but is not meant to
 26 provide an all-inclusive list of products . . . for each product category." Dkt. 222-1 at 6.

27 ⁷ Under 21 C.F.R. § 101.12(d), the reference amount for a substitute food shall be the same as for the
 28 food for which it is offered as a substitute.

⁸ For example, while one might attempt to argue that a breakfast cereal bar is a substitute for a bowl

To prevail on their “substitute” argument, Plaintiffs would have to be able to prove that Parkay Spray can be “used *interchangeably* with another food that it resembles [allegedly butter or margarine], i.e., that it is organoleptically, physically, *and* functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an ‘imitation.’” 21 C.F.R. § 101.13(d) (emph. added). Courts and the FDA have confirmed that the term “substitutes” should be interpreted narrowly. *See, e.g., Rahman v. Mott’s LLP*, No. 13-cv-3482, 2014 U.S. Dist. LEXIS 11767, at *17 (N.D. Cal. Jan. 29, 2014) (explaining that FDA has taken position that “no salt added” canned corn is substitute for regular canned corn, not frozen corn, and that “sodium free Italian bread” is a substitute for Italian bread). And based on the plain text of the regulation, it is clear that a substitute food is not one that just shares certain similarities with another. It must be able to be used interchangeably—that is, indistinguishably—with another product and it must be similar along all three of the listed dimensions (organoleptically, physically, and functionally). Here, there is **no dispute** that:

- **Functionally**, Parkay Spray cannot be used similarly to butter or margarine with respect to baking. George Decl., Ex. 2 (Hottenstein Decl. ¶ 34 (in this respect “Parkay Spray is functionally unlike butter and margarine”)); Ex. 19 (Bulent Binbuga Rule 26(a)(2)(C) Disclosure (“Binbuga Discl.”) at 7-8).
- **Functionally**, Parkay Spray cannot be used similarly to butter or margarine with respect to greasing pans. George Decl., Ex. 2 (Hottenstein Decl. ¶ 33 (Parkay Spray is a “relatively poor choice” as compared to butter and margarine)); Ex. 19 (Binbuga Discl. at 7-8).
- **Functionally**, Parkay Spray is unlike butter or margarine in that it lacks butter/margarine’s versatility and cannot be used to make sauces like Béchamel or Hollandaise. George Decl., Ex. 3 (Hottenstein Dep. 240:11-20); Ex. 19 (Binbuga Discl. at 7-8).
- **Physically**, Parkay Spray exists in a different state than butter or margarine. George Decl., Ex. 2 (Hottenstein Decl. at Table 1 (rating the viscosity of butter as “solid fat” and Parkay Spray closer to a “liquid oil”)); Ex. 19 (Binbuga Discl. at 6-7).
- **Physically**, Parkay Spray has different primary ingredients than butter/margarine and a significantly lower fat content. George Decl., Ex. 2 (Hottenstein Decl. at Table 2); Ex. 19 (Binbuga Discl. at 7).
- **Physically**, butter or margarine cannot be dispensed via a pump mechanism like Parkay Spray. George Decl., Ex. 3 (Hottenstein Dep. 242:2-6); Ex. 19 (Binbuga Discl. at 7).
- **Organoleptically**, Parkay Spray and butter have distinctly different appearances, with respect to hue and intensity of hue. George Decl., Ex. 2 (Hottenstein Decl. at Table 1, ¶ 15).

of cereal, there is no reason to consider whether the breakfast cereal bar is a substitute for foods in the category “Breakfast cereals, ready-to-eat” given that there is a more specific category that clearly applies on its face (“Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars”).



- **Organoleptically**, Parkay Spray has a different taste profile than butter/margarine, insofar as Parkay Spray's flavor intensity is 1.5 to 2 times greater than butter/margarine; Parkay Spray is orders of magnitude saltier; the predominant tasting note of butter and margarine is "buttery" while the predominant note for Parkay Spray is supposedly "cardboard." In fact, butter is "yummy" with "***no cardboard*** or waxy off notes" and margarine is "not tasty but not overly unpleasant," while Parkay Spray is, according to Plaintiffs' expert, "highly unpleasant" and has an "[u]ncomfortable intense flavor." George Decl., Ex. 2 (Hottenstein Decl. at Table 1); *see also* Ex. 19 (Binbuga Discl. at 6).

Accordingly, even accepting Plaintiffs' expert's report as true and viewing the evidence in the light most favorable to Plaintiffs, they cannot establish that Parkay Spray and butter/margarine can be used interchangeably. Those food products cannot be used for the same functional purposes, are physically and compositionally dissimilar, and look and taste different. Whatever other similarities Plaintiffs' expert has drawn out in her report—butter/margarine and Parkay Spray are both refrigerated products, butter/margarine and Parkay Spray may contain coloring agents, butter/margarine and Parkay Spray all contain milkfat, etc.—they are insufficient to show that the products are interchangeable. Conagra and the FDA are thus correct in choosing the Spray Type product category.

b. If There Is Any Ambiguity Regarding the Correct Product Category for Parkay Spray, FDA's Interpretation Must Control

Critically, in a letter from the Director of the ONFL, the FDA "agree[d] with [the] conclusion that this product belongs in the 'Fats and Oils: Spray types' product category with a RACC of 0.25 g" and accordingly "clarif[ied] that the appropriate RACC for Parkay Spray is 0.25 g." George Decl., Ex. 1. Under the long-standing doctrine of *Auer* deference—recently reaffirmed by the U.S. Supreme Court in *Kisor*—the FDA's interpretation is entitled to controlling weight. As such, Conagra uses the correct RACC, Parkay Spray contains no fat or calories under the FDA's rounding rules at the appropriate serving size, the challenged claims are expressly authorized by statute, and all of Plaintiffs' claims are preempted. Indeed, this case is exemplary of why the express preemption doctrine exists —

1 if Plaintiffs' claims were not preempted Conagra could be found legally liable *and enjoined* from
2 doing exactly what the FDA has instructed it to do.

3 As explained by the U.S. Supreme Court in *Kisor*, applying *Auer* deference, a court should
4 defer to an agency's interpretation of its own rules and regulations where: (i) "the regulation is
5 genuinely ambiguous"; (ii) the agency's reading is reasonable; (iii) and the "character and context of
6 the agency interpretation entitles it to controlling weight." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2414-16
7 (2019). This deference reflects several animating principles: Congress presumably would want the
8 agency to play the primary role in resolving regulatory ambiguities; the agency is typically better
9 positioned to exercise judgment grounded in policy concerns, especially given its unique substantive
10 expertise in the field; and deferring to the agency prevents inconsistent results by elevating uniform
11 administrative decisions over piecemeal litigation. *Id.* at 2412-14. Here, all three prongs of the *Kisor*
12 test are present and the principles underlying *Auer* deference are particularly acute. Accordingly, the
13 FDA's interpretation from its September 2019 letter should be given controlling weight.

14 ***i. If the Court Does Not Conclude 21 C.F.R. § 101.12 Unambiguously Provides***
15 ***That Parkay Spray Is a "Spray-Type" Fat or Oil, It Must Find the Regulation***
16 ***Is Genuinely Ambiguous***

17 A statute or regulation is "genuinely ambiguous" if the court concludes the interpretive
18 question has "no single right answer" after exhausting all the "traditional tools" of construction. *Kisor*
19 *v. Wilkie*, 139 S. Ct. 2400, 2415 (2019). As explained above, the traditional tools of construction all
20 point towards Conagra's interpretation—e.g., only the "Spray type" category applies on its face, that
21 category is the most specific category that could potentially apply, the structure of the regulation shows
22 that product form matters and only the most specific category should apply, etc.

23 But even if the Court found these factors were not dispositive, it could not conclude that the
24 "single right answer" to the interpretive question is that Parkay Spray is a butter/margarine substitute
25 falling in the "Butter, margarine, oil, shortening" category. Plaintiffs' own expert admits, as detailed
26 above, that Parkay Spray and butter/margarine cannot be used interchangeably, exist in different
27 forms, taste and look different, and are made up of different ingredients. *See supra* Section V.A.1.a
28 As a result, Parkay Spray does not meet the definition of "substitute." *See* 21 C.F.R. § 101.13(d).
Moreover, another federal court, applying the "traditional tools of construction" reached the

conclusion that a competitor product with the same material characteristics was properly classified in the category “Fat and Oils: Spray Type,” and the manufacturer was “required” to use the corresponding RACC for that category. *Pardini*, 2014 U.S. Dist. LEXIS 7900, at *15 (reaching conclusion based on plain language of statute and interpretive maxim that more specific category applies over more general category). It is difficult to see how the Court could conclude that there is a “single right answer” given the well-reasoned *Pardini* decision. In fact, this Court has already said that, in light of *Pardini*, there “is substantial ground for a difference of opinion” in interpreting 21 C.F.R. § 101.12(b). In other words, if the “Fats and Oils: Spray types” category isn’t the *single* right answer to the interpretive question, it is at least one of “multiple reasonable meanings” and the regulation is genuinely ambiguous. *Kisor*, 139 S. Ct. at 2419.

ii. The Agency’s Interpretation Is Reasonable

If genuine ambiguity remains, the agency’s interpretation “must still be ‘reasonable.’” *Id.* at 2415. In other words, it “must come within the zone of ambiguity the court has identified after employing all its interpretive tools” to be entitled to deference. *Id.* at 2416. “The text, structure, history, and so forth at least establish the outer bounds of permissible interpretation.” *Id.* Again, the interpretive tools identified in Section V.A.1.a—including the regulations’ text and structure—lead to the FDA’s interpretation. The FDA’s interpretation is also consistent with that of another federal court. There can thus be no dispute that the FDA’s interpretation is within the “zone of ambiguity.”

iii. The “Character and Context” of FDA’s Interpretation Entitles It to Controlling Weight

While there is no exhaustive test for determining whether the “character and context” of an interpretation is entitled to *Auer* deference, the U.S. Supreme Court has identified several “important markers”: (i) the interpretation is an “authoritative” position of the agency, not an “ad hoc statement not reflecting the agency’s views”; (ii) the agency’s interpretation “must in some way implicate its substantive expertise”; and (iii) the agency’s interpretation reflects its “fair and considered judgment” insofar as it is not a “convenient litigating position” or a “new interpretation” unfairly sprung on regulated parties. *Kisor*, 139 S. Ct. at 2416-18. Once again, these markers are present here.

First, the FDA letter is signed by Dr. Balentine, the Director of the ONFL. As set forth in the

1 FDA Staff Manual, the ONFL is responsible not only for developing regulations related to “food and
 2 nutrition labeling,” but also for issuing “advisory opinions for matters within the scope of the
 3 responsibility of the Office.” George Decl., Ex. 4 (FDA Staff Manual Guides). Accordingly, if anyone
 4 at FDA were to issue an interpretive opinion regarding the proper RACC category for a given product,
 5 it would be someone from within that Office. Moreover, the letter was not issued by some low-level
 6 employee in that Office, but rather the Director, who is only one step removed from reporting directly
 7 to the Office of the Commissioner. In fact, courts have recognized that letters issued by the Director
 8 of the ONFL—and Dr. Balentine specifically—are entitled to *Auer* deference. In *Karim v. Naked*
 9 *Juice Co. of Glendora, Inc.*, for example, the court found that a letter signed by Dr. Balentine was
 10 entitled to *Auer* deference after noting that he was an “official[] who served with the FDA since 2015”
 11 (who was familiar with the regulations at issue) as opposed to some “more junior agency employee[]”
 12 or “lower-level FDA employee[].” No. BC649121, 2018 Cal. Super. LEXIS 4453, *10-11 (Cal. Super.
 13 Ct. Apr. 3, 2018); *see also, e.g., Perez v. Kroger Co.*, 336 F. Supp. 3d 1137, 1144 (C.D. Cal. 2018)
 14 (affording *Auer* deference to a letter sent by Dr. Ballentine in his capacity as Director of the ONFL).
 15 Because the Director of the ONFL issued the letter, the letter represents the FDA’s authoritative view.

16 **Second**, the FDA’s interpretation implicates its substantive experience. Indeed, “it is the
 17 agency, not the courts or consumers, who set [RACC] standards” in the first place, based on food
 18 consumption surveys performed by the agency. *Pardini*, 2014 U.S. Dist. LEXIS 7900, at *15; *see*
 19 *also* 21 C.F.R. § 101.12(a) (describing steps FDA took to develop and calculate RACCs). Where food
 20 consumption data was insufficient, the FDA relied on its expertise and administrative judgment in
 21 parsing other sources of information to arrive at the appropriate RACC. 21 C.F.R. § 101.12(a)(5). In
 22 addition to determining the specific reference amounts, the FDA was responsible for proposing and
 23 adopting the actual RACC product categories and for grouping products together based on FDA’s
 24 determination that “their customarily consumed amounts are similar.” 58 Fed. Reg. 2229, 2240 (Jan.
 25 6, 1993); *see also* 21 C.F.R. § 101.12(a)(9) (in devising RACC product categories, “FDA sought to
 26 ensure that foods that have similar dietary usage, product characteristics, and customarily consumed
 27 amounts have a uniform reference amount”). For these reasons, manufacturers “who are not sure
 28 about which product category their specific products belong” are instructed to “consult with the

agency.” *Id.* at 2241. And, consistent with that instruction and its substantive expertise, the FDA regularly issues directions concerning the appropriate RACC category for particular food products. *See, e.g., id.* at 2240 (rejecting proposal for 1 oz serving size for fish because it was not supported by the food consumption data collected by FDA). In short, the entire RACC taxonomy is predicated on FDA’s expertise—in assessing and analyzing consumption data, in selecting the appropriate reference amount, in developing the appropriate number and types of food categories, and in grouping products together based on similar characteristics and customarily consumed amounts—and interpreting the regulation in the context of Parkay Spray would likewise call on that expertise. *See Kisor*, 139 S. Ct. at 2417 (explaining that TSA’s substantive experience would be implicated in determining whether jar of truffle pâté was properly classified as liquid, gel, or aerosol for purposes of carry-on rule).

Third, FDA’s interpretation is not a “convenient litigation” position, nor is it a new interpretation upending regulated parties’ settled expectations. “Courts will decline to give an agency’s interpretation *Auer* deference when it appears that the interpretation is ‘nothing more than a convenient litigating position.’” *Perez*, 336 F. Supp. 3d at 1146 (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012)). But for the FDA to have taken a “convenient litigating position” there must be pending litigation in which the agency was involved that required FDA to take a position. *Id.* A mere response to a letter, no matter how “strongly worded” does not “result in the FDA taking a litigation position.” *Id.*; *see also, e.g., Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 930 (Cal. 2004) (deferring to FDA’s letter response to citizen’s petition that plaintiff had filed while case was pending). In addition, FDA’s interpretation is not a “new interpretation . . . that creates ‘unfair surprise’ to regulated parties.” *Kisor*, 139 S. Ct. at 2418. FDA’s interpretation is consistent with that of industry members and the prior court to consider the issue. *See Pardini*, 2014 U.S. Dist. LEXIS 7900, at *15.

iv. The Animating Principles of Auer Deference Are Particularly Acute Here

Auer deference rests heavily on the “well-known benefits of uniformity in interpreting genuinely ambiguous rules.” *Kisor*, 139 S. Ct. at 2413. The Supreme Court has repeatedly noted Congress’s preference “for resolving interpretive issues by uniform administrative decision, rather than piecemeal by litigation.” *Id.* Even where a rule appears “accessible” on its face, like the RACC

rule here, agency deference is justified because these rules “too may give rise to more than one eminently reasonable reading.” *Id.* at 2414. “*Auer* deference thus serves to ensure consistency in federal regulatory law, for everyone who needs to know what it requires.” *Id.* Here, consistency is of particular concern given the *Pardini* decision. If this Court were to rule in Plaintiffs’ favor, two materially indistinguishable products would be subject to different regulations based on decisions not by courts all over the country, but by courts in the same judicial district.

2. In the Alternative, the Court Should Defer to FDA’s Primary Jurisdiction

In its Motion to Dismiss Order, this Court previously declined to defer to FDA’s primary jurisdiction in regulating food products and serving sizes, finding there were no “recent developments that would mediate in favor of disturbing [Judge Tigar’s] prior ruling” on primary jurisdiction. Dkt. 231 at 18. Since the Motion to Dismiss Order, the FDA issued its guidance letter to Conagra. That change in circumstances now warrants deferring to FDA’s primary jurisdiction.

As the Court previously recognized, “[t]he primary jurisdiction doctrine is prudential and allows a court to stay proceedings or dismiss a complaint without prejudice so that the relevant agency can resolve an issue within its ‘special competence.’”⁹ Dkt. 231 at 18 (citing *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008)). The “central focus of the primary jurisdiction doctrine [is] the desirability of uniform determination and administration of federal policy.” *Kelley v. Wwf Operating Co.*, No. 1:17-cv-117, 2017 U.S. Dist. LEXIS 86971, at *13 (E.D. Cal. June 5, 2017) (citation omitted). Applying the doctrine of primary jurisdiction in the context of alleged mislabeling accordingly not only “allows the Court to benefit from the FDA’s expertise on food labeling,” but also “will ensure uniformity in administration of the regulations.” *Id.* (citations omitted).

Courts have been particularly keen to dismiss or stay cases under the doctrine of primary jurisdiction where FDA has expressed an interest in the subject matter of the litigation, usually through its issuance of letters to food manufacturers. *See, e.g., Kelley*, 2017 U.S. Dist. LEXIS 86971, at *13; *Hood*, 2013 U.S. Dist. LEXIS 97836, at *19. For example, in *Kelley*, the court deferred to the primary

⁹ As explained above, determining the appropriate RACC category falls within FDA’s special competence. Also, courts have routinely invoked the primary jurisdiction doctrine in the labeling context to avoid “undercutting the FDA’s expert judgments and authority.” *Hood v. Wholesoy & Co.*, No. 12-cv-5550, 2013 U.S. Dist. LEXIS 97836, at *14 (N.D. Cal. July 12, 2013) (collecting cases).

jurisdiction of FDA in a case involving whether almond milk products were misbranded because they were allegedly nutritionally inferior substitutes for dairy milk, but were not labeled as “imitation milk.” 2017 U.S. Dist. LEXIS 86971, at *3. In doing so, the court noted that FDA had been asked to weigh in on the issue (through a citizen petition and Congressional request) and that FDA had issued warning letters to other producers of soymilk showing that “FDA has, at the very least, been aware that producers label soymilk as such and has, to some extent, taken a stance on whether that is appropriate.” *Id.* at *12-14. Accordingly, “[t]he issue is therefore on the FDA’s radar” and “[t]he FDA should, at the very least, have the opportunity to decide whether it will address the issue.”¹⁰ Here, as in *Kelley*, FDA has been asked to weigh in on the correct RACC for Parkay Spray and has, through its September 6, 2019 letter “taken a stance” that 0.25 g is the correct RACC. Even if the Court is disinclined to afford the letter controlling weight, the Court should at least recognize that the issue is on FDA’s radar and FDA has chosen to speak on the issue. As in *Kelley*, FDA should then, at the very least, be given the opportunity to decide how to further address the issue. This is particularly true here, where Plaintiffs seek injunctive relief at odds with FDA’s express instructions to Conagra.

B. Plaintiffs’ Claims Fail for Additional, Independent Reasons on the Merits

1. Erin Allen’s Claims Based on the Post-2009 Label Must Be Dismissed Because She Cannot Show Actual Reliance

All of class representative Erin Allen’s claims require a showing of actual reliance.¹¹ Here, it is undisputed that Ms. Allen did not view the “per serving” portion of the post-2009 challenged claim (i.e., 0g Fat · Zero Calories *Per Serving*), and was not aware of that language until *after* she filed her

¹⁰ The *Kelley* court also found that “the issue of whether Defendant’s products (or any other plant-based ‘milk’) should be deemed an ‘imitation’ [i.e., a nutritionally inferior substitute] . . . fits squarely within the FDA’s authority.” 2017 U.S. Dist. LEXIS 86971, at *11. The question Plaintiffs insist the Court answers—whether Parkay Spray should be deemed a “substitute” for butter/margarine—likewise fits squarely within FDA’s authority and should be left for FDA to answer.

¹¹ See *Sukonik v. Wright Med. Tech., Inc.*, No. 14-cv-08278, 2015 U.S. Dist. LEXIS 177502, at *41 (C.D. Cal. Jan. 26, 2015) (noting reliance requirement for fraudulent misrepresentation and fraudulent concealment under California law); *Vanella v. Ford Motor Co.*, No. 3:19-cv-07956-WHO, 2020 U.S. Dist. LEXIS 32151, at *22 (N.D. Cal. Feb. 24, 2020) (Orrick, J.) (breach of express warranty under California law requires reliance); *Victor v. R.C. Bigelow, Inc.*, No. 13-cv-02976-WHO, 2014 U.S. Dist. LEXIS 34550, at *14 (N.D. Cal. Mar. 14, 2014) (Orrick, J.) (actual reliance required for standing under CLRA, UCL, and FAL for claims based on alleged misrepresentations like Plaintiffs’ claims here); *Frenzel v. Aliphcom*, No. 14-cv-03587-WHO, 2015 U.S. Dist. LEXIS 88751, at *30 (N.D. Cal. July 7, 2015) (Orrick, J.) (explaining that plaintiff cannot maintain causes of action under CLRA, UCL, and FAL based on a statement that he did not rely on in making his purchase).

lawsuit. As a result, she cannot prove actual reliance as to the post-2009 formulation of the claim.

It is axiomatic that a plaintiff “cannot have relied on what he never saw.” *Burch v. CertainTeed Corp.*, 34 Cal. App. 5th 341, 353 (Cal. Ct. App. 2019); *see also English v. Apple Inc.*, No. 3:14-cv-01619-WHO, 2017 U.S. Dist. LEXIS 4869, *39 (N.D. Cal. Jan. 11, 2017) (Orrick, J.) (granting summary judgment in defendant’s favor because plaintiff admitted she never read the terms and conditions containing the alleged misrepresentations). According to Ms. Allen’s sworn testimony, prior to filing her lawsuit, she “did not see the ‘per serving’” portion of the challenged claims, and at all times prior to bringing this lawsuit (after which point she can no longer claim justifiable reliance), she purportedly only relied on the representation that Parkay Spray contained “0 Grams Fat, 0 Calories.” George Decl., Ex. 6 (8/28/14 Allen Dep. 86:3-4, 85:24-25, 86:5-22). The Court has now twice recognized that the difference between the pre- and post-2009 label is potentially dispositive and “requires that each class be divided into two time periods—one before and another after the label change.” Dkt. 267 at 15; Dkt. 150 at 2. Plaintiff cannot show that she actually relied on a claim falling in the second time period (with the “per serving” qualifier), and therefore her causes of action based on the post-2009 label must be dismissed. As explained in Conagra’s contemporaneously filed motion for decertification, without a class representative for those post-2009 claims, that entire subclass should be decertified as well.

2. Plaintiffs’ Fraud Claims and Request for Exemplary Damages Fail Because Plaintiffs Cannot Establish Scienter

Plaintiffs’ fraudulent concealment and intentional misrepresentation claims require a showing of scienter. *Bains v. Moores*, 91 Cal. Rptr. 3d 309, 318 (Cal. Ct. App. 2009). An award of exemplary or punitive damages likewise “requires a finding of scienter.” *Roman Catholic Bishop of Oakland v. Super. Ct. of Alameda Cty.*, 28 Cal. Rptr. 3d 355, 368 (Cal. Ct. App. 2005) (citing Cal. Civ. Code, § 3294). Courts in this Circuit have repeatedly held that a defendant could not have acted with the requisite scienter where it adopted a reasonable interpretation of an ambiguous statute or regulation. *See, e.g., United States v. Zatica*, 244 F. App’x 799, 801 (9th Cir. 2007) (no scienter because defendant adopted one of two reasonable interpretations); *U.S. ex rel. Krawitt v. Infosys Techs. Ltd.*, 342 F. Supp. 3d 958, 967 (N.D. Cal. 2018) (establishing scienter is exceptionally difficult “when falsity turns on a

1 disputed interpretive question”).¹²

2 Here, as described above, the RACC regulation is, at minimum, ambiguous (if not dispositive
3 in Conagra’s favor). Conagra adopted an eminently reasonable interpretation of that regulation—
4 indeed, the same interpretation arrived at by the FDA and another federal court—and Plaintiffs have
5 presented no authority or guidance that would have put Conagra on notice that its interpretation that
6 Parkay Spray is a “Spray-type” fat or oil was unwarranted or unreasonable. While Plaintiffs will
7 surely point to consumer complaints about Conagra’s labeling and Conagra’s purported unwillingness
8 to disclose the fat and caloric content of an entire bottle of Parkay Spray, *see* Dkt. 244 at 15-16, that
9 is irrelevant to the question of scienter—i.e., whether Conagra knew the RACC category it was using
10 was incorrect and its label representations were therefore false. Under the RACC regulatory scheme,
11 manufacturers are tasked with selecting the correct RACC product category independently of
12 consumer behavior, expectations, or desires. 58 Fed. Reg. 2229, 2273 (Jan. 6, 1993) (manufacturers
13 “cannot deviate” from reference amounts based on consumption data). Absent evidence that Conagra
14 knew or should have known that its RACC interpretation was incorrect—as opposed to evidence that
15 consumers were upset about the serving size applied to Parkay Spray within the regulatory scheme—
16 Plaintiffs cannot prove their fraud claims or recover exemplary damages. *See Krawitt*, 342 F. Supp.
17 3d at 967 (no scienter even where defendant told conduct may be illegal because there was no guidance
18 or case law contradicting defendant’s reasonable interpretation of ambiguous statute).

19 **3. The Product Label Discloses Required, Objective Facts, Remediating Any Potential** 20 **Consumer Confusion**

21 In their Motion for Class Certification, Plaintiffs claim that “despite being over 40% fat, Parkay
22 Spray’s bottle proclaims it contains no fat or calories.” Dkt. 244 at 12. Plaintiffs know that Parkay
23 Spray contains “over 40% fat” not due to any sophisticated scientific testing of the product, but
24 because the product plainly discloses on its front label “that it is ‘44% vegetable oil’ (which is pure
25 fat).” *Id.* at 12. In other words, the same bottle that supposedly misleads them also serves as the basis

26
27 ¹² These cases often arise in the False Claims Act context. Notably, “[t]he scienter for common law
28 fraud is somewhat greater than that required by the FCA’s scienter requirement.” *U.S. ex rel. Jordan*
v. Northrop Grumman Corp., No. 95-cv-2985, 2002 U.S. Dist. LEXIS 26674, *30 (C.D. Cal. Aug. 5,
2002).

1 for their knowledge that the product contains “over 40% fat.” Further, the Nutrition Panel discloses
 2 that the second and third most predominant ingredients in the product are soybean oil and buttermilk.
 3 As numerous courts have recently confirmed, a reasonable consumer cannot be misled as a matter of
 4 law where, as here, a product label plainly discloses facts that dispel alleged consumer confusion. *See,*
 5 *e.g., Truxel v. Gen. Mills Sales, Inc.*, No. 16-cv-04957, 2019 U.S. Dist. LEXIS 144871, at *11 (N.D.
 6 Cal. Aug. 13, 2019); *In re: 100% Grated Parmesan Cheese Mktg. & Sales Practices Litig.*, 275 F.
 7 Supp. 3d 910, 923 (N.D. Ill. 2017) (“100% Grated Parmesan Cheese” not misleading because “readily
 8 accessible ingredient panel” disclosed presence of non-cheese ingredients).

9 **C. Plaintiffs’ Damages Methodology Fails as Matter of Law, So Conagra Is Entitled to**
 10 **Summary Judgment**

11 Summary judgment in Conagra’s favor is also proper because Plaintiffs have not introduced
 12 competent evidence of the *fact* of their damages. *Robi v. Five Platters, Inc.*, 918 F.2d 1439, 1443 (9th
 13 Cir. 1990). Plaintiffs claim they are entitled to damages equivalent to “the difference between the
 14 market value (purchase price) of the Product (with the Claims) and the market value of the Product
 15 (without the claims).” George Decl., Ex. 7 (2/28/20 Weir Decl. at ¶ 67). While the purchase price of
 16 the product with the claims is known, Plaintiffs must offer some valid methodology for calculating the
 17 market value of the product without the claims—i.e., the purchase price of the product in the but-for
 18 world. In other words, to prove the fact of their damages, Plaintiffs must calculate the but-for market
 19 price and show that it would have been lower than the actual market price. Plaintiffs turn to conjoint
 20 analysis—a survey-based methodology—to do so.

21 As the Ninth Circuit has explained, “plaintiffs can measure class-wide damages using methods
 22 that evaluate what a consumer would have been willing to pay for the product had it been labeled
 23 accurately”—like conjoint analysis—but such methods “must, however, reflect supply-side
 24 considerations and marketplace realities that would affect product pricing.” *Zakaria v. Gerber Prods.*
 25 *Co.*, 755 F. App’x 623, 624 (9th Cir. 2018) (emphasis added). Otherwise, the methodology will only
 26 reflect “how much consumers subjectively valued” the product (demand) and not “the actual market
 27 price” required to prove and calculate damages (demand and supply). *Id.* at 625. By now, it is
 28 undisputed that a conjoint analysis, without more, does not and cannot measure market price. The

question that has confounded courts, however, is whether a given expert has taken adequate additional steps so that their conjoint analysis is capable of outputting market prices. The answer here is no.

1. It Is Well-Accepted in the Literature and the Law That Conjoint Analysis Is Only Capable of Measuring Willingness to Pay (i.e., Demand)

“Conjoint analysis is a statistical technique capable of using survey data to determine how consumers value a product’s individual attributes—often called the market’s willingness to pay.” *Saavedra v. Eli Lilly & Co.*, No. 2:12-cv-9366, 2014 U.S. Dist. LEXIS 179088, at *12 (C.D. Cal. Dec. 18, 2014). Survey respondents are asked to choose between various product profiles with varying attribute levels, and then statistical analysis is performed to isolate the separate value consumers placed on each attribute, called “partworths.” *See In re NJOY, Inc. Consumer Class Action Litig.*, 120 F. Supp. 3d 1050, 1073 (C.D. Cal. 2015). In Plaintiffs’ conjoint analysis, their expert, Michael Dennis, then uses the Sawtooth Software “market simulator” tool to find the prices at which 50% of survey respondents favor the product with the challenged claims and 50% of survey respondents favor the product without the claims—the price differential will be what Plaintiffs claim as damages. Dkt. 187 at ¶ 68. By only collecting and analyzing data provided by consumers regarding their willingness to purchase the spray product, Plaintiffs’ conjoint analysis methodology looks only to the demand side of the equation; it in no way incorporates or analyzes supply factors (such as competition in the marketplace, production constraints, etc.). *See* George Decl. Ex. 8 (Ugone Decl. at ¶¶ 50-73). This basic proposition has been recognized both in the literature concerning conjoint analysis and by numerous court decisions.¹³

2. Plaintiffs’ Experts Do Not Otherwise Account for Supply-Side Factors

This Court has previously heard challenges to conjoint methodology—specifically that plaintiffs’ experts had failed to account for supply-side factors—but noted in that case that defendant

¹³ *See, e.g.*, George Decl., Ex. 9 (Bryan Orme & Keith Chrzan, *Becoming an Expert in Conjoint Analysis* 194 (2017)) (“Finally, one can use conjoint simulations to find WTP [willingness to pay].”)); George Decl., Ex. 10 (Bryan Orme, *Getting Started with Conjoint Analysis* 88 (2010) (explaining that conjoint “may be used to assess buyer price sensitivity and willingness to pay”); *see also In re NJOY*, No. 14-cv-428, 2016 U.S. Dist. LEXIS 24235, at *17 (C.D. Cal. Feb. 2, 2016); *Saavedra*, 2014 U.S. Dist. LEXIS 179088, at *12; *Morales v. Kraft Foods Grp., Inc.*, No. 2:14-cv-04387, 2017 U.S. Dist. LEXIS 97433, at *62 (C.D. Cal. June 9, 2017); *Zakaria v. Gerber Prod. Co.*, No. 2:15-cv-200, 2017 U.S. Dist. LEXIS 221124, at *57 (C.D. Cal. Aug. 9, 2017), *aff’d*, 755 F. App’x 623 (9th Cir. 2018).

1 had cited “no cases rejecting conjoint analyses for failures to account for these particular issues.”
 2 *Krommenhock v. Post Foods, LLC*, No. 16-cv-04958-WHO, 2020 U.S. Dist. LEXIS 40463, at *48
 3 (N.D. Cal. Mar. 9, 2020). But, in a spate of recent decisions, courts have rejected conjoint analyses
 4 (including analyses proffered by Plaintiffs’ expert, Colin Weir) for precisely that reason. *See In re*
 5 *GM*, 407 F. Supp. 3d 212, 237, 241 (S.D.N.Y. 2019) (applying California law and granting summary
 6 judgment); *Schechner v. Whirlpool Corp.*, No. 2:16-cv-12409, 2019 U.S. Dist. LEXIS 171642, at *19
 7 (E.D. Mich. Aug. 13, 2019) (rejecting Weir’s conjoint analysis and denying class certification); *Beaty*
 8 *v. Ford Motor Co.*, No. 17-cv-5201, 2020 U.S. Dist. LEXIS 23670, at *19 (W.D. Wash. Feb. 11, 2020)
 9 (finding “better-reasoned cases reject the sort of damages calculations that [Weir] proposes”).

10 In rejecting these conjoint analyses, the courts also rejected the playbook that Plaintiffs will
 11 undoubtedly turn to here in attempting to overcome the fundamental deficiencies of their
 12 methodology, including: (i) claiming that they go above and beyond a traditional conjoint analysis and
 13 actually incorporate supply-factors by using “actual market prices that prevailed during the Class
 14 Period” in their survey, as well as the actual quantity of Parkay Spray sold, which is fixed as a matter
 15 of history; (ii) citing to the “Supply Side Considerations” section of Mr. Weir’s report as proof that
 16 they did consider supply factors; (iii) misleadingly referring to the “market simulator” to suggest that
 17 they have calculated a “market price”; and (iv) when all else fails, string-citing the line of district court
 18 cases that have accepted conjoint analysis. The Court should reject each of these attempts to explain
 19 away Plaintiffs’ methodological shortcomings.

20 **First**, Plaintiffs’ methodology requires comparing two states of the world: the actual world
 21 (where price and quantity are known and Parkay Spray was sold with the challenged claims) and the
 22 but-for world (where Plaintiffs’ model must predict price and quantity sold, and Parkay Spray was
 23 sold without the challenged claims). Using actual prices and quantity from the real-world in no way
 24 accounts for supply in the but-for world. *See Schechner*, 2019 U.S. Dist. LEXIS 171642, at *20 (using
 25 actual, historical prices is inadequate to address supply-side factors in the but-for world because
 26 historical transactions reflect only historical supply-side factors, not what the “prevailing market
 27 conditions would have been absent the alleged wrongful conduct”; “Weir needed to estimate both
 28 historical prices and the prices absent the alleged conduct, but he failed to do the latter”); *In re GM*,

407 F. Supp. 3d at 240 (using actual, historical quantity is tantamount to assuming that supply is fixed regardless of price—a “fundamentally flawed” assumption); George Decl. Ex. 8 (Ugone Decl. at ¶¶ 64-68). Nor does it make sense that Plaintiffs could address supply-side factors in the *but-for world* by simply importing prices and quantity from the *actual world*.

Second, Weir’s discussion of supply-side factors, which is never converted into any inputs used in Dennis’s model, does not amount to accounting for supply-side considerations. “Needless to say, however, merely including a section titled ‘Consideration of the Supply Side’ in an expert report . . . does not cut it if the analysis reflected in that expert report does not actually include meaningful consideration of supply-side factors.” *In re GM*, 407 F. Supp. 3d at 239.

Third, the “market simulator” Dennis and Weir refer to has nothing to do with a market in the sense of an exchange between buyers and sellers. It is merely a tool used to find where *demand* for the product with the challenged claims equals *demand* for the product without the claims. *See* Dkt. 187 at ¶ 68. As confirmed by Bryan Orme, the President of Sawtooth Software, the software’s “market simulator” provides “an estimate of WTP”—willingness to pay. George Decl., Ex. 9; George Decl. Ex. 8 (Ugone Decl. at ¶¶ 55-58). Supply considerations, like data on competitors, are never inputted.

Fourth, as explained in more detail in *In re GM*, prior cases accepting similar conjoint methodologies “did so with little or no consideration of the market price issue,” erroneously found that the conjoint analysis *did* take into consideration supply factors, or “are distinguishable, unpersuasive, or both.” *In re GM*, 407 F. Supp. 3d at 238.

Because Plaintiffs rely solely on their conjoint analysis for damages purposes—“that is, Plaintiffs point to no other evidence from which a factfinder could find damages based on a difference in value—there is an ‘absence of evidence’ on an ‘essential element’ of Plaintiffs’ claims for such damages” and “the Court must grant [Conagra’s] motion for summary judgment on the . . . claims to the extent they seek damages measured as the difference in value between [the product] as bargained-for and [the product] as received.” *Id.* at 241.

VI. CONCLUSION

For the foregoing reasons, Conagra respectfully requests that the Court grant its Motion for Summary Judgment and dismiss Plaintiffs’ claims with prejudice.

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